

What is claimed is:

Sub E2  
1. A lactose-free pharmaceutical composition which comprises an optically pure enantiomer of fluoxetine, 5 or a pharmaceutically acceptable salt thereof, and at least one non-lactose pharmaceutically acceptable excipient.

2. A solid pharmaceutical composition which comprises an optically pure enantiomer of fluoxetine, or a 10 pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable excipient, wherein said excipient is not lactose.

3. The composition of claim 1, wherein said non- 15 lactose pharmaceutically acceptable excipient is a binder, a filler, or a mixture thereof.

4. The composition of claim 2, wherein said pharmaceutically acceptable excipient is a binder, a filler, 20 or a mixture thereof.

5. The composition of claim 3 or 4 wherein said binder is a starch.

25 6. The composition of claim 3 or 4 wherein said binder is a cellulose.

Sub B  
A1  
30 7. The composition of claim 5 wherein said starch is selected from the group consisting of corn starch, potato starch, pre-gelatinized starch and a mixture thereof.

Sub E2  
8. The composition of claim 6 wherein said cellulose is selected from the group consisting of ethyl cellulose, cellulose acetate, carboxymethyl cellulose 35 calcium, sodium carboxymethyl cellulose, methyl cellulose, hydroxypropyl methyl cellulose, microcrystalline cellulose and a mixture thereof.

Sub E2/ 9. The composition of claim 3 or 4, which further comprises a lubricant, disintegrant, or mixtures thereof.

10. The composition of claim 1 or 2, wherein said 5 enantiomer of fluoxetine is (R)-fluoxetine.

11. The composition of claim 1 or 2, wherein said enantiomer of fluoxetine is (S)-fluoxetine.

Sub E2/ 12. The composition of claim 1 or 2, wherein said pharmaceutical composition is substantially free of all mono- or di-saccharides.

13. A chemically stable compressed tablet free of 15 lactose which comprises racemic fluoxetine, an optically pure enantiomer of fluoxetine or a pharmaceutically acceptable salt thereof, and at least one pharmaceutically acceptable excipient.

Sub E2/ 14. A chemically stable compressed tablet free of 20 lactose which comprises about 1% to about 50% by weight of racemic fluoxetine, an optically pure enantiomer or a pharmaceutically acceptable salt thereof, and about 99% to 25 acceptable excipient.

Sub E2/ 15. The compressed tablet of claims 13 or 14 wherein said tablet does not contain a disintegrant.

Sub E2/ 16. The compressed tablet of claim 13 or 14 30 wherein said tablet does not dissolve in less than three minutes when subjected to the DISSOLUTION TEST.

Sub E2/ 17. The composition of claim 13 or 14, wherein 35 said fluoxetine is present in an amount from about 1 mg to about 200 mg.

18. The composition of claim 17, wherein said fluoxetine is present in an amount of about 2 mg to about 100 mg.

5 19. The composition of claim 13 or 14, wherein said fluoxetine enantiomer is optically pure (R)-fluoxetine.

20. The composition of claim 13 or 14, wherein said fluoxetine enantiomer is optically pure (S)-fluoxetine.  
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21. A solid compressed tablet consisting essentially of racemic fluoxetine, an optically pure enantiomer or a pharmaceutically acceptable salt thereof, and microcrystalline cellulose and pre-gelatinized starch.  
SUB A3

15 22. The solid pharmaceutical composition of claim 13 or 14, wherein said compressed tablet is sterile, anhydrous and non-hygroscopic.  
Sub (3)

20 23. An anhydrous solid pharmaceutical composition which comprises racemic fluoxetine, an optically pure enantiomer of racemic fluoxetine or a pharmaceutically acceptable salt thereof, and one or more pharmaceutically acceptable excipients.

25 24. The composition of claim 23 wherein said composition does not contain lactose.  
sub D, Sub E27

25 25. The composition of claim 23 or 24 wherein said composition is a compressed tablet.  
30

26. The composition of claim 23 or 24 wherein said fluoxetine enantiomer is optically pure (R)-fluoxetine.

35 27. The composition of claim 23 or 24 wherein said fluoxetine enantiomer is optically pure (S)-fluoxetine.

Sub 27  
Sub C  
28. The composition of claim 23 or 24 wherein said composition is non-hygroscopic.

29. The composition of claim 1, 13, 14, 21, 23, or 24 wherein said pharmaceutically acceptable salt is a hydrochloride salt.

Sub 10  
Sub 4  
30. A stable solid pharmaceutical unit dosage form which comprises racemic fluoxetine, an optically pure enantiomer of racemic fluoxetine, or a pharmaceutically acceptable salt thereof, and one or more pharmaceutically acceptable excipients wherein said dosage form is not a capsule or gel cap.

15 31. The unit dosage form of claim 30 wherein said fluoxetine enantiomer is optically pure (R)-fluoxetine.

32. The unit dosage form of claim 30 wherein said fluoxetine enantiomer is optically pure (S)-fluoxetine.

20 33. A solid compressed tablet substantially free of lactose which comprises an optically pure enantiomer of fluoxetine, or a pharmaceutically acceptable salt thereof, and at least one pharmaceutically acceptable excipient which  
Sub 27  
25 is not lactose.

34. A disintegrating tablet substantially free of lactose which comprises an optically pure enantiomer of fluoxetine, or a pharmaceutically acceptable salt thereof,  
30 and at least one pharmaceutically acceptable excipient which is not lactose.

35. A method of treating depression in a mammal which comprises the oral administration of a therapeutically  
35 effective amount of a composition of claims 1, 2, 13, 14, 21, 23, 24, 30, 33 or 34 to said mammal.